

इंटरनेट

मानक

Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 1984-1 (2003): Injection Containers for Injectables and Accessories, Part 1: Injection Vials Made of Glass Tubing [MHD 12: Hospital Equipment]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

BLANK PAGE



भारतीय मानक

इंजेक्शन द्रव्यों हेतु शीशियाँ तथा उपसाधन

भाग 1 काँच नली से बनी इंजेक्शन शीशियाँ

(दूसरा पुनरीक्षण)

Indian Standard

**INJECTION CONTAINERS FOR INJECTABLES AND
ACCESSORIES**

PART 1 INJECTION VIALS MADE OF GLASS TUBING

(Second Revision)

ICS 11.040.20

© BIS 2003

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

NATIONAL FOREWORD

This Indian Standard (Part 1) (Second Revision) which is identical with ISO 8362-1 : 1989 'Injection containers for injectables and accessories — Part 1 : Injection vials made of glass tubing' issued by the International Organization for Standardization (ISO) was adopted by the Bureau of Indian Standards on the recommendations of the Medical Instruments and Disposables Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1961 and revised in 1971 to incorporate modifications in respect of limits of alkalinity, uniformity in dimensions of neck finishes, closer dimensional tolerances and merger of the requirements for vaccine phials covered earlier under IS 490 : 1967 'Specification for vaccine phials (*first revision*)'. Second revision of this Standard has been undertaken with a view to align its requirements with the corresponding ISO 8362-1 : 1989 and adopt it as a dual number Indian Standard.

The purpose of this part of standard is to specify the dimensions, capacities, form and requirements of glass vials intended for medical use. Containers made from glass tubing are considered to be suitable for the packaging and storage of injectable preparations until they are administered for medicinal purposes. Such containers may be made from different types of glass which can affect the chemical resistance properties. For example, those made from borosilicate glass will have a very high level of chemical resistance, whereas others made from soda-lime-silica glass will have a lower, but adequate, chemical resistance for the purpose for which they are intended. The chemical resistance of the internal surface of containers made from soda-lime-silica glass can be improved by a treatment during production to produce a chemical resistance equal to that of those made from borosilicate glass for single use. This level of chemical resistance will be maintained as long as the interior surface is not destroyed by chemical attack, in which case it will be reduced to that of untreated soda-lime-silica glass.

Because containers may be made from different types of glass and because it is the chemical behaviour of the internal surface, which is important when they are filled with injectable preparations, it is essential to specify test procedures by which this performance can be measured. The procedures recommended in this part of the standard will allow this performance based on the hydrolytic resistance, to be measured and, from the result of measurement, it is possible to classify containers into their correct category. The procedure also allows containers to be tested and to determine, after an intermediate stage, whether the hydrolytic resistance is produced by the composition of the glass as a material or by a treatment of the internal surface.

The text of International Standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'; and
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

Indian Standard
**INJECTION CONTAINERS FOR INJECTABLES AND
ACCESSORIES**

PART 1 INJECTION VIALS MADE OF GLASS TUBING
(Second Revision)

1 Scope

This part of ISO 8362 specifies the form, dimensions and capacities of glass vials for injectable preparations. It also specifies the material from which such containers shall be made and the performance requirements of those containers.

This part of ISO 8362 applies to colourless or amber glass containers made from borosilicate or soda-lime-silica glass, made from glass tubing, whether internally surface-treated or not, and intended to be used in the packaging, storage or transportation of products intended for injection.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 8362. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 8362 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 719: 1985, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification.*

ISO 720: 1985, *Glass — Hydrolytic resistance of glass grains at 121 °C — Method of test and classification.*

ISO 1101: 1983, *Technical drawings — Geometrical tolerancing — Tolerancing of form, orientation, location and run-out — Generalities, definitions, symbols, indications on drawings.*

ISO 4802-1: 1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1: Determination by titration method and classification.*

ISO 4802-2: 1988, *Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2: Determination by flame spectrometry and classification.*

3 Definitions

For the purposes of this part of ISO 8362, the definitions given in ISO 4802-1 and ISO 4802-2 apply.

Table 1 – Dimensions, overflow capacity and mass

Dimensions in millimetres

Size designation of injection vial	Overflow capacity ml		a	d ₁		d ₂ ^{+0,2} -0,3	d ₃ max.	d ₄ ±0,2	h ₁		h ₂ min.	h ₃		r ₁ ≈	r ₂ ≈	s ₁ tol.	s ₂ min.	t max.	Mass g ≈		
		tol.			tol.					tol.			tol.								
2R	4	±0,5	1	16	±0,2	13	10,5	7	35	±0,5	23	8	±0,5	2,5	1,5	1	±0,04	0,7	5		
4R	6		22	20		16,5	12,6	45	40		33	9		3,5	2				0,7	0,7	6,1
6R	10		1,2					±0,2	45		27										8,5
8R	11,5	45			32				3,5	2	9,4										
10R	13,5	±1	24	±0,2	20	16,5	12,6	60	45	31	9	±0,05	0,7	0,7	1	±0,05	1	10,2			
15R	19							65	46	3,5	2							12,8			
20R	25	±1,5	1,5	30	±0,3	17,5	12,6	55	±0,7	35	10	±0,75	5,5	2,5	1,2	±0,05	1	17,4			
25R	30,5							65	45	5,5	2,5	1,2	±0,05	1	20						
30R	36							75	55	5,5	2,5	1,2	±0,05	1	22,7						

4.2 Designation

Designation example of an injection vial, size 10 (10R), made of amber glass (br) tubing of hydrolytic resistance container class ISO 4802 - HC 1 (1) complying with the requirements specified in this part of ISO 8362:

Vial ISO 8362-1 10R - br - 1

5 Material

Colourless (cl) or amber (br) borosilicate glass¹⁾ or soda-lime-silica glass¹⁾ of one of the following hydrolytic resistance grain classes:

- ISO 720 - HGA 1
- ISO 719 - HGB 3 or ISO 720 - HGA 2

shall be used.

NOTE — A change in the chemical composition of the glass material or of the colouring oxides should be notified to the user at least nine months in advance.

6 Performance

6.1 Injection vials shall not contain seed or bubbles to an extent which will interfere with the visual examination of the contents.

6.2 Injection vials shall have a sealing surface, which is flat and free from ripples or undulations which would affect the sealing performance of the closure.

7 Requirements

7.1 Hydrolytic resistance

When tested in accordance with ISO 4802-1 or ISO 4802-2, the hydrolytic resistance of the internal surface of injection vials shall comply with the requirements specified for one of the following hydrolytic resistance container classes:

- ISO 4802 - HC 1
- ISO 4802 - HC 2
- ISO 4802 - HC 3.

7.2 Annealing quality

The injection vials shall be annealed so that the maximum residual stress does not produce an optical retardation exceeding 40 nm per millimetre of glass thickness, when the vials are viewed in a strain viewer.

8 Marking

The number of pieces and the designation according to 4.2 together with the name or symbol of the manufacturer shall be shown on the package.

Further information may appear subject to agreement.

(Continued from second cover)

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their place are listed below along with their degree of equivalence for the editions indicated:

<i>International Standard</i>	<i>Corresponding Indian Standard</i>	<i>Degree of Equivalence</i>
ISO 719 : 1985	IS 2303 (Part 1/Sec 1) : 1994 Grading glass for alkalinity : Part 1 Hydrolytic resistance, Section 1 Hydrolytic resistance of glass grains at 98°C — Method of test and classification (<i>first revision</i>)	Equivalent
ISO 720 : 1985	IS 2303 (Part 1/Sec 2) : 1994 Grading glass for alkalinity : Part 1 Hydrolytic resistance, Section 2 Hydrolytic resistance of glass grains at 121°C — Method of test and classification (<i>first revision</i>)	do
ISO 1101 : 1983	IS 8000 (Part 1) : 1985 Geometrical tolerancing on technical drawings : Part 1 Tolerances of form, orientation, location and run-out and appropriate geometrical definitions (<i>first revision</i>)	Identical

The Technical Committee responsible for the preparation of this standard has reviewed the provisions of ISO 4802-1 : 1988 'Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 1 : Determination by titration method and classification' and ISO 4802-2 : 1988 'Glassware — Hydrolytic resistance of the interior surfaces of glass containers — Part 2 : Determination by flame spectrometry and classification', referred in this adopted standard and decided that these are acceptable for use in conjunction with this standard.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Review of Indian Standards

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards : Monthly Additions'.

This Indian Standard has been developed from Doc : No. MHD 12 (2306).

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110 002
Telephones : 2323 0131, 2323 3375, 2323 9402

Telegrams: Manaksanstha
(Common to all offices)

Regional Offices :

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg
NEW DELHI 110 002

Telephone

{ 2323 7617
2323 3841

Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Kankurgachi
KOLKATA 700 054

{ 2337 8499, 2337 8561
2337 8626, 2337 9120

Northern : SCO 335-336, Sector 34-A, CHANDIGARH 160 022

{ 60 3843
60 9285

Southern : C. I. T. Campus, IV Cross Road, CHENNAI 600 113

{ 2254 1216, 2254 1442
2254 2519, 2254 2315

Western : Manakalaya, E9 MIDC, Marol, Andheri (East)
MUMBAI 400 093

{ 2832 9295, 2832 7858
2832 7891, 2832 7892

Branches : AHMEDABAD. BANGALORE. BHOPAL. BHUBANESHWAR. COIMBATORE.
FARIDABAD. GHAZIABAD. GUWAHATI. HYDERABAD. JAIPUR. KANPUR.
LUCKNOW. NAGPUR. NALAGARH. PATNA. PUNE. RAJKOT. THIRUVANANTHAPURAM.
VISAKHAPATNAM.